K002388

AUG 2 5 2000

Attachment 7

510(k) Summary

CyberCare EHC500 Desktop Patient Station

The following information is in accordance with 21 CFR 807.92.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

CyberCare, Inc. (now known as CyberCare Technologies, Inc.)
7840 Roswell Rd.
Bldg. 300, Suite 320
Atlanta, GA 30350
Tel (770) 352-9540
Fax (770) 392-4950

Contact Person: J. Terry Drury, Executive Vice President

Date Prepared: August 3, 2000

Name of Device

CyberCare EHC500 Desktop Patient Station

Device Classification/Classification Panel

21 CFR § 890.3710 ILQ Class II
Powered Communication System

21 CFR § 870.1130 DXN Class II
Noninvasive Blood Pressure Measuring Systems

21 CFR § 880.2910 FLL Class II
Clinical Electronic Thermometer

21 CFR § 870.2700 DQA Class II
Noninvasive Pulse Oximeters

Cardiovascular Devices Panel

Predicate Device

CyberCare EHC400 Desktop Patient Station

Intended Use

The CyberCare EHC500 Desktop Patient Station (EHC500) is a patient monitoring system intended for providing out-of-hospital vital signs monitoring of adult patients or pediatric patients with the assistance and supervision of an adult. The EHC500 is intended to work in conjunction with the EHC600 Care Provider Station (EHC600) providing two-way video, audio and data communication between the two stations. The EHC500 monitors the following physiologic functions: blood pressure (sphygmomanometer), oxygen saturation (pulse oximeter), heart rate (pulse oximeter), and temperature (electronic oral thermometer).

Description of the Device/Substantial Equivalence

The CyberCare EHC500 Desktop Patient Station (EHC500) is a patient monitoring system intended for providing out-of-hospital vital signs monitoring of adult patients or pediatric patients with the assistance and supervision of an adult. The EHC500 is intended to work in conjunction with the CyberCare EHC600 Care Provider Station providing two-way video, audio and data communication between the two stations. The EHC500 monitors the following physiologic functions: blood pressure (sphygmomanometer), oxygen saturation (pulse oximeter), heart rate (pulse oximeter), and temperature (electronic oral thermometer).The EHC500 is comprised of a touch screen computer unit, a microphone, speaker, camera devices to permit the patient to see and hear the remote care provider when necessary, and the following measuring devices: (1) sphygmomanometer; (2) pulse oximeter; and (3) electronic oral thermometer.

With the exception of one modification, the Company's EHC500, covered by this submission, is identical to the CyberCare EHC400 Desktop Patient Station (EHC400) that has already been cleared by FDA. The EHC500 has the same general intended use, same principles of operation, and same technological characteristics as the previously cleared predicate EHC400. The only difference is that the EHC500's touch screen computer and vital signs unit are integrated into one physical housing, whereas the EHC400's physical housing consists of two units: a touch screen computer and a vital signs unit. Thus, the EHC500 is substantially equivalent to its predicate device, the EHC400.

Performance Data

The EHC500 uses currently available technology found in legally marketed devices. Testing, to confirm that the EHC500 would perform as intended, was conducted at two levels. Non-clinical bench testing using simulators was used to test each function. Clinical testing using volunteers was conducted to demonstrate that the EHC500 continues to meet its specifications and perform as intended to verify performance of SpO_2, heart rate, NIBP, and oral temperature.

The EHC500 meets applicable standards for performance and EMC compliance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2000

Mr. J. Terry Drury
Executive Vice President
CyberCare Technologies, Inc.
7840 Roswell Road
Building 300, Suite 320
Atlanta, GA 30350

Re: K002388
CyberCare EHC500 Desktop Patient Station
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: August 3, 2000
Received: August 4, 2000

Dear Mr. Drury:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have

under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosures

Indications for Use Form

510(k) Number (if known): K002388

Device Name: CyberCare EHC500 Desktop Patient Station

Indications for Use:

The CyberCare EHC500 Desktop Patient Station (EHC500) is a patient monitoring system intended for providing out-of-hospital vital signs monitoring of adult patients or pediatric patients with the assistance and supervision of an adult. The EHC500 is intended to work in conjunction with the CyberCare EHC600 Care Provider Station providing two-way video, audio and data communication between the two stations. The EHC500 monitors the following physiologic functions: blood pressure (sphygmomanometer), oxygen saturation (pulse oximeter), heart rate (pulse oximeter), and temperature (electronic oral thermometer).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109)

for Mark N Melkerson

Division of Cardiovascular & Respiratory Devices
510(k) Number K002388